

Appl. No. : 10/734,606
Filed : December 11, 2003

REMARKS

In response to the Restriction Requirement mailed on May 18, 2005, Applicants hereby provisionally elect to prosecute the invention set forth in Group I, Claims 1-9 and 25-39 in this application with strong traverse. The claims of Group I, as noted by the Examiner, are drawn to an antibody formulation and a kit comprising the antibody formulation classified in class 435, subclass 810. In addition, as required by the Restriction Requirement, Applicants further elect the following species: mannitol (excipient) with traverse. Claims 1-3, 5-9, 25-33 and 35-39 read on the elected species.

The Examiner argued that the restriction of the inventions claimed in Groups I and II was proper because inventions I and II are related as a process of making and a product made. However, the Examiner stated that the antibody compositions can be formulated by various other biochemical and recombinant methods not recited in Group II, and thus are patentably distinct. Applicants strongly disagree.

Claim 1 from Group I recites a "solid formulation comprising at least one antibody, and histidine." Claim 10 from Group II recites a method of preparing an antibody in a solid formulation by "mixing at least one antibody with a stabilizing amount of histidine to form a mixture." It is unclear to Applicants how the product of Claim 1 can be made by another materially different process than that of Claim 10. Claim 1 recites a formulation of an antibody and histidine. Claim 10 recites a method of making a formulation by mixing an antibody and histidine. The fact that antibodies can be manufactured by other methods is moot as the method of manufacturing the antibody itself is not part of the claimed method. For this reason, Applicants respectfully request withdrawal of this rejection and examination of all pending claims.

Moreover, the examination of Groups I and II together will not impose a serious burden on the Examiner because of the intimate connection between the claimed product and its method of manufacture. Indeed, the Examiner *must* examine the entire application if the search and examination can be made without serious burden (M.P.E.P. §803.01). Furthermore, no conservation of USPTO resources would be realized if the restriction requirement as asserted is maintained. For this reason, Applicants respectfully request withdrawal of the rejection and examination of all pending claims.

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Similarly, the consideration of mannitol together with the other excipients recited in Claims 3, 18, and 33 will not impose a serious burden on the Examiner. Accordingly, Applicants respectfully request withdrawal of the species election and examination of all of excipients recited in the pending claims.

Should the Examiner refuse to examine all of the claims together, Applicants note that Claims 1-2, 5-9, 31-32 and 35-39 are generic for Group 1. Upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. Additionally, Applicants reserve the right to prosecute any withdrawn claims and any non-elected species in divisional applications, if necessary, under the provisions of 35 U.S.C. § 121.

The undersigned has made a good faith effort to respond to the Restriction Requirement. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is invited to call the undersigned attorney to resolve such issues promptly. No fees are seen as being necessary for filing this Response. However, the Commissioner is authorized to charge any fees in connection with this paper to Deposit Account No. 11-410.

Respectfully submitted,

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